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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/003,047	01/05/1998	ALBERT J J VAN OOYEN	261922003302	8520

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01/31/2005

SYNGENTA BIOTECHNOLOGY, INC.  
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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/003,047

**Applicant(s)**

VAN OUYEN ET AL.

**Examiner**

David H Kruse

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,42,48,51,54,56-58 and 61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,42,48,51,54,56-58 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 07/849,422.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Remarks filed 15 November 2004.
2. Applicant has perfected the claim of priority in the response filed 15 November 2004 by amendment to the first line of the specification.
3. The Objection to the specification is withdrawn in view of Applicant's remarks (page 5 of the response).
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1, 42, 48, 51, 54-58 and 61 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated from the reasons of record as set forth in the last Office action mailed 20 July 2004. Applicant's arguments filed 15 November 2004 have been fully considered by they are not found to be persuasive.

Applicants replies that in order to advance prosecution of certain embodiments of the invention, the claims have been amended to recite the microbial endo-1,3- $\beta$ -glucanase or endo-1,4- $\beta$ -glucanase to more particularly point out and distinctly claim the present invention (page 5 of the Remarks).

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This argument is not found to be persuasive for the reasons of record in the previous Office action. The specification on page 6, lines 31-32, only describes general groups of endo-1,3- $\beta$ -glucanase or endo-1,4- $\beta$ -glucanase enzyme, and EC 3.2.1.6 encompasses enzymes with both endo-1,3- $\beta$ -glucanase and endo-1,4- $\beta$ -glucanase activities. The art teaches that substrate specificity of glucanases can be of critical importance in the function such enzymes, and that standard methods of determining enzymatic activity of glucanases at the time of Applicant's invention often do not address the issue of substrate specificity (see Esen 1993, in  $\beta$ -Glucosidases Biochemistry and Molecular Biology, Esen editor, American Chemical Society, Washington, D.C., pages 1-3, cited in the previous Office action). Applicant does not describe what structural features or specific function of an endo-1,3- $\beta$ -glucanase or endo-1,4- $\beta$ -glucanase enzyme is critical to produce the required effect of the claimed method, i.e. the saccharide composition of the plant or plant organ is increased as a result of expression of the microbial endo-1,3- $\beta$ -glucanase or endo-1,4- $\beta$ -glucanase enzyme.

6. Claims 1, 42, 48, 51, 54-58 and 61 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated from the reasons of record as set forth in the last Office action mailed 20 July 2004. Applicant's arguments filed 15 November 2004 have been fully considered by they are not found to be persuasive.

Applicants state that they disagree with this rejection, however, in order to advance prosecution of certain embodiments of the invention, the claims have been amended to recite the microbial endo-1,3- $\beta$ -glucanase or endo-1,4- $\beta$ -glucanase to more particularly point out and distinctly claim the present invention (page 6 of the Remarks).

This argument is not found to be persuasive for the reasons of record in the previous Office action. Esen (1993) teaches that the substrate specificity of an endo-glucanase *in vitro* may not reflect the substrate specificity *in vivo* (page 2, 3<sup>rd</sup> paragraph). Applicant provides no working examples of the claimed method, vector or transgenic plant of the claims. Given the teachings of Esen as to the state of the art at the time of Applicant's invention and the general knowledge of one of skill in the art at the time of Applicant's invention, one could not predict what the effect of any given microbial endo-1,3- $\beta$ -glucanase or endo-1,4- $\beta$ -glucanase would have in a transgenic plant without an actual reduction to practice. Given such an unpredictable outcome of the claimed method, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use a myriad of plants transformed with a myriad of recombinant expression constructs containing nucleic acid sequences encoding microbial endo-1,3- $\beta$ -glucanases or endo-1,4- $\beta$ -glucanases as broadly claimed.

#### ***Claim Rejections - 35 USC § 102***

7. Claims 1, 27, 28, 51, 54-58 and 61 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Borriss *et al* (WO 90/09436, published 23 August 1990) taken with the evidence of Hofemeister *et al* (1986, Gene Vol. 49, pages 117-187). This rejection

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is repeated from the reasons of record as set forth in the last Office action mailed 20 July 2004. Applicant's arguments filed 15 November 2004 have been fully considered by they are not found to be persuasive.

Applicants argue that Borriss et al. taken with the evidence of Hofemeister et al. describe genetic constructs and transgenic plants comprising a microbial (1,3-1,4)- $\beta$ -glucanase. Applicants argue that this reference does not describe the presently claimed invention using microbial endo-1,3- $\beta$ -glucanase or endo-1,4- $\beta$ -glucanase, therefore, Borriss taken with Hofemeister do not describe each and every element of the presently claimed invention, and do not anticipate (page 6 of the Remarks).

This argument is not found to be persuasive because Applicants' specification defines endo-1,3- $\beta$ -glucanases as encompassing the enzyme class EC 3.2.1.6 on page 6 of the specification, the microbial (1,3-1,4)- $\beta$ -glucanase of Borriss et al is a member of EC 3.2.1.6 enzymes.

### ***Double Patenting***

8. Claims 1, 27, 28, 42, 48, 51, 54-58 and 61 remain rejected under the judicially created doctrine of double patenting over claims 5 and 17 of U. S. Patent No. 5,705,375, published 6 January 1998, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. This rejection is repeated from the reasons of record as set forth in the last Office action mailed 20 July 2004, and has been modified upon additional review of the claims of U. S. Patent No. 5,705,375. Applicants state in the response filed 15 November 2004 that upon allowance of subject matter of the claims, Attorney or Applicants will submit a terminal disclaimer to

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overcome this rejection (page 6 of the Remarks). The Examiner notes Applicants' statement, the rejection is maintained for the reasons of record.

9. Claims 1, 27, 28, 42, 48, 51, 54-58 and 61 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 10 and 11 of U.S. Patent No. 5,543,576, published 6 August 1996. This rejection is repeated from the reasons of record as set forth in the last Office action mailed 20 July 2004, and has been modified upon additional review of the claims of U.S. Patent No. 5,705,375. Applicants state in the response filed 15 November 2004 that upon allowance of subject matter of the claims, Attorney or Applicants will submit a terminal disclaimer to overcome this rejection (page 6 of the Remarks). The Examiner notes Applicants' statement, the rejection is maintained for the reasons of record.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

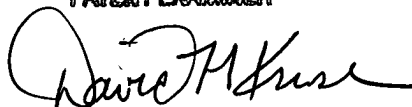
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11. No claims are allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.  
PATENT EXAMINER



David H. Kruse, Ph.D.  
27 January 2005

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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